July 15, 2025

Kerecis Limited
Skuli Magnusson
Vice President (Regulatory Affairs, Quality & Clinical Affairs)
Sundastraeti 38
P.O. Box 151
Isafjordur, 400
Iceland

Re: K251844
Trade/Device Name: Kerecis SurgiBind (50241)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OXH
Dated: June 12, 2025
Received: June 16, 2025

Dear Skuli Magnusson:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

TEK N. LAMICHHANE -S

Tek N Lamichhane, PhD
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
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Infection Control Devices
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Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251844

Device Name
Kerecis SurgiBind (50241)

Indications for Use *(Describe)*
For implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair, or reinforcement in plastic or reconstructive surgery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – K251844

Premarket Notification Submission (510(k) Summary)

Submitter Information

Sponsor Name:	Kerecis Limited
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Sponsor Telephone:	+354-419-8000
Establishment Registration:	301060025
Applicant:	Skuli Magnusson,
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Email Direct:	sm@kerecis.com
Primary Contact Person:	Skuli Magnusson,
Contact Title:	VP of Regulatory Affairs, QA & Clinical Affairs
Email Direct:	sm@kerecis.com
Date Summary Prepared:	July 15, 2025

Device Information

Trade Name (Proprietary):	Kerecis SurgiBind (50241)
FDA Device Code:	OXH
Categorization:	Mesh, surgical, collagen, plastic and reconstructive surgery
Device Class:	Class II, 21 CFR § 878.3300 – Surgical Mesh

Predicate Device

Company Name:	Kerecis
Device Name (Proprietary):	Kerecis Reconstruct
Device 510(k):	K202430

Reference Device

Company Name:	Cook Biotech Inc.
Device Names (Proprietary):	Biodesign Anal Fistula Plug, Biodesign Fistula Plug, Biodesign Plastic Surgery Matrix, Biodesign Tissue Graft
Device 510(k):	K191696

Device Description

Kerecis SurgiBind (50241) is a part of a family of devices manufactured by Kerecis® Limited. The device is lyophilized, terminally sterilized, fish skin medical device comprised of biocompatible, resorbable fish skin

(Wild North Atlantic Cod). The device is intended for single use only. Kerecis Reconstruct is now commercially marketed as Kerecis SurgiBind due to a name change. For clarity, this submission will refer to the device as Kerecis SurgiBind, except when specifically referencing the predicate device (K202430). This information is shown in Table 1.

Table 1: Subject device of this submission

Product Name	510(k) Proprietary Name/Device Name	510(k) number
Kerecis SurgiBind	Kerecis Reconstruct	K202430

The subject device remains physically identical to its predicate device, both in design and packaging, as well as for indications for use. The only difference between the subject device and its predicate device is in the device labeling, with the subject device having additional rehydration fluid options included in their instructions for use (IFUs).

Intended Use / Indications for Use

The indications for use of K202430 is presented in Table 2. This submission does not introduce any changes in the indications for use.

Table 2: Indications for Use

Product name	Indications for Use
Kerecis Reconstruct (K202430)	For implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair, or reinforcement in plastic or reconstructive surgery

Description of Modification

The only modification from the predicate device is in the device labeling. The modification that triggered this submission is the inclusion of additional rehydration options in the instructions for use (IFU). In addition to saline and Ringer's solution (which are the rehydration fluids in the predicate device), autologous body fluids (such as blood) are being added as potential rehydration fluid options for the subject device of this submission.

Kerecis is implementing this modification in response to interest within the field regarding the use of these fluids for device rehydration.

Technological characteristics and substantial Equivalence

The technological characteristics of the subject device of this submission and the proposed predicate device (K202430), are identical in that they are animal-based products suitable for tissue reinforcement. They also share identical device design and principle of operation. The following items are provided to demonstrate substantial equivalence to the predicate devices:

- Risk analysis summary

- Sterilization justification
- Shelf-life justification
- Biocompatibility justification
- Bench testing

Table 3: Substantial Equivalence comparison table

Device name	Kerecis SurgiBind **(Subject Devices)**	Kerecis Reconstruct **(Predicate Device)**	Biodesign Anal Fistula Plug, Biodesign Fistula Plug, Biodesign Plastic Surgery Matrix, Biodesign Tissue Graft **(Reference Devices)**	**Comparison**
Manufacturer	Kerecis Limited	Kerecis Limited	Cook Biotech Incorporated	N/A
510(k)	K251844	K202430	K191696 (Bundled)	N/A
Prescription, single use only	Unchanged from predicate device	Yes	Yes	Same
Product Code		OXH	OXN, OXH, FTM (Bundled Submission)	Same
Indications for Use		For implantation to reinforce soft tissue where weakness exists, in patients requiring soft tissue repair, or reinforcement in plastic or reconstructive surgery.	Biodesign Anal Fistula Plug: For implantation to reinforce soft tissue where a rolled configuration is required, for repair of anal, rectal and enterocutaneous fistulas. Biodesign Fistula Plug: For implantation to reinforce soft tissue for repair of recto-vaginal or anorectal fistulas. Biodesign Plastic Surgery Matrix: For implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic or reconstructive surgery.	Same as predicate

Device name	Kerecis SurgiBind **(Subject Devices)**	Kerecis Reconstruct **(Predicate Device)**	Biodesign Anal Fistula Plug, Biodesign Fistula Plug, Biodesign Plastic Surgery Matrix, Biodesign Tissue Graft **(Reference Devices)**	**Comparison**
			Biodesign Tissue Graft: For implantation to reinforce soft tissue.	
Materials		Atlantic Cod Fish Skin.	Porcine small intestinal submucosa: (constituents of the extracelluar matrix)	Same as predicate
Supplied sterile?		Yes	Yes	Same
Sterilization Method		Ethylene Oxide	Ethylene Oxide	Same
Intended for single use?		Yes	Yes	Same
Rehydration fluid(s)	Sterile Saline, Ringer's solution and autologous body fluids (such as blood)	Sterile Saline and Ringer's solution	All Devices in the bundle: Sterile saline and autologous body fluids	Different to predicate, comparable to reference devices

Performance Testing

Performance testing for this 510(k) submission was largely leveraged from the Kerecis predicate device, as the subject device shares the same intended use, materials, and manufacturing process. As a result, performance testing is not required, except for rehydration and suture retention tests using autologous body fluid. These specific tests were conducted to address the only modification for the subject device, i.e., the inclusion of autologous body fluids (such as blood) as rehydration agents. The results confirmed that device performance remains consistent and comparable to the predicate device, supporting a determination of substantial equivalence.

Conclusion

For the purposes of determining substantial equivalence under section 513(i) of the FD&C Act (21 U.S.C. § 360c(i)), Kerecis® SurgiBind (the subject device) shares the same intended use, functions, mode of action, and fundamental scientific technology as the predicate device. Additionally, the subject device is composed of the same materials and is manufactured using identical processes as the predicate device. The sole modification is the inclusion of autologous body fluids (such as blood) as optional rehydration fluids in the device's Instructions for Use (IFU). Because there are no changes to the fundamental scientific technology or intended use, and verification and validation activities have been completed, there is sufficient evidence to demonstrate that the subject device performs comparably to the predicate device currently marketed for the same intended use.

It is concluded that the subject device is substantially equivalent to the predicate device.